

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE K-V PHARMACEUTICAL
COMPANY SECURITIES LITIGATION

Civil Action No. 4:11-CV-01816-AGF

**INDIVIDUAL DEFENDANTS GREGORY J. DIVIS, JR., SCOTT GOEDEKE,
AND THOMAS S. MCHUGH'S MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT OF THEIR MOTION TO DISMISS THE
CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

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<u>Exhibit #</u>	<u>Description</u>
A.	Form 10-K of K-V Pharmaceutical Company for the fiscal year ended March 31, 2010.
B.	Transcript of K-V Pharmaceutical Company Investor Conference Call, February 14, 2011.
C.	Form 8-K of K-V Pharmaceutical Company filed with the Securities and Exchange Commission on February 14, 2011.
D.	Form 8-K of K-V Pharmaceutical Company filed with the Securities and Exchange Commission on March 8, 2011.
E.	Press Release from K-V Pharmaceutical Company, “K-V Pharmaceutical Company Announces Comprehensive Patient Assistance Program for Makena™,” March 8, 2011.
F.	<i>FY 2012 FDA Budget, Hearing Before the S. Subcomm. on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the S. Comm. on Appropriations, 112th Cong. (Mar. 17, 2011)</i>
G.	Press Release from Senator Sherrod Brown, “Brown Leads Effort to Demand Federal Investigation Into Price-Gouging of Pre-Term Labor Drug for Expectant Mothers,” March 17, 2011.
H.	Press Release from FDA, “FDA Statement on Makena,” March 30, 2011.
I.	Press Release from K-V Pharmaceutical Company, “Ther-Rx Corporation Takes Action to Further Ensure High-Risk Women Are Able to Access FDA-Approved Makena™,” April 1, 2011.
J.	Sheldon T. Bradshaw, Kyle Sampson, & Brian J. Wesoloski, <i>Did FDA Apply a Remedy Worse Than the Disease In Refusing To Clear the Market of Unapproved Versions of Makena?</i> , Food & Drug Policy Forum, June 8, 2011.

TABLE OF ABBREVIATIONS

17P	Compounded drugs that contain hydroxyprogesterone caproate
CAC	Consolidated Amended Class Action Complaint
FDA	The Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FTC	Federal Trade Commission
NDA	New Drug Application
ODA	Orphan Drug Act

I. INTRODUCTION

K-V Pharmaceutical Company planned to introduce an FDA-approved drug that reduced the risk of pre-term births. Its executives stated that the drug, Makena®, would be introduced, explained that the FDA had granted K-V market exclusivity over the drug, disclosed the initial planned list price, and described the efforts that they would undertake to provide access to the drug to low-income women and women without insurance. K-V's executives also stated their belief that K-V's FDA market exclusivity would lead pharmacies that were compounding batches of competing non-FDA-approved drugs to comply with the applicable laws and regulations and cease selling their drugs at a lower price than the proposed price for Makena. But politicians reacted negatively to the planned list price for Makena and pressured the FDA into taking an unprecedented action—issuing an affirmative statement that it would not enforce K-V's statutory exclusivity over Makena against competing compounded drug products—an action that K-V contends to this day was unlawful. As a result of the FDA's public announcement that it would not enforce K-V's market exclusivity, K-V's stock price declined.

Plaintiff alleges that the Individual Defendants committed securities fraud when they failed to predict to their investors the chain of events that led to the FDA's decision. But “[c]orporate officials need not be clairvoyant.” *In re Navarre Corp. Sec. Litig.*, 299 F.3d 735, 743 (8th Cir. 2002). To the contrary, “they are only responsible for revealing those material facts reasonabl[y] available to them.” *Id.* Plaintiff does not allege that Defendants knew their statements were necessarily false at the time that they were made, save for a smattering of conclusory statements by confidential witnesses, which at most show disagreement with management and should be entirely disregarded. *Minn. Firefighters’ Relief Ass’n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1030 (8th Cir. 2011).

The securities laws provide “safe harbors” for forward-looking statements, and the alleg-

edly misleading statements challenged by Plaintiff fall squarely within the safe harbors. Most prominently, K-V disclosed to its investors meaningful cautionary language that warned of precisely the market exclusivity and product acceptance issues that eventually caused the Company's stock price to decline. The only challenged statement that is not accompanied by cautionary language is not actionable because it was not made to investors.

Even if Defendants' statements were actionable, Plaintiff has failed to allege facts demonstrating that the statements were false. Defendants' statements were not false, as they accurately summarized FDA's regulations and enforcement policies for their investors, described their plans to promote access to Makena, and projected K-V's expected revenues.

Plaintiff also fails to allege facts that would support a "strong inference" of scienter. She points to no actionable motive for Defendants to commit securities fraud. The most compelling inference from the facts is that Defendants spent \$250 million and three years to obtain government approval for Makena because they thought it would succeed; not so that they could boost the company's stock price for a few weeks by lying to the market.

Finally, Plaintiff has failed to demonstrate that the challenged statements caused her losses. The purported corrective disclosures do not reveal the truth about any fraudulent misrepresentations, but only that some parties reacted negatively to K-V's previously-announced list price for Makena. This does not reveal fraud.

Plaintiffs' deficient Complaint should be dismissed. Because these pleading defects cannot be cured by amendment, the dismissal should be with prejudice.

II. BACKGROUND

A. FDA's Statutory and Regulatory Regime

Under the ODA, 21 U.S.C. §§ 360aa-ee, an "orphan drug," as applicable here, is a drug used to treat a disease or condition affecting fewer than 200,000 people in the United States.

Congress enacted the ODA as an amendment to the FDCA, 21 U.S.C. § 301-399d, in order to create incentives for the development of drugs relating to illnesses where “so few individuals are affected” that “a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss.” Orphan Drug Act, Pub. L. No. 97-414, §1(b)(4), 96 Stat. 2049, 2049 (1983). The principal incentive offered by the ODA is a seven-year period of market exclusivity to the first sponsor of an approved orphan drug. The market exclusivity gives the sponsor a chance to recoup its costs and make a profit, and functions much like a patent. *See* 21 U.S.C. § 360cc(a); *Genentech, Inc. v. Bowen*, 676 F. Supp. 301, 302-06 (D.D.C. 1987).

Compounding pharmacies are generally not subject to the same stringent requirements regarding drug approval, manufacturing, and labeling that apply to pharmaceutical manufacturers. Traditional pharmacy compounders have “tailored [drugs] to the needs of an individual patient,” for example, a patient who is unable to take an FDA-approved drug because of an allergy to an inactive ingredient. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002). Congress permits compounding pharmacies to operate provided that they do not engage in drug manufacturing and distribution beyond an individualized scale. 21 U.S.C. § 353a. A pharmacy must not compound “regularly or in inordinate amounts” drugs that “are essentially copies of a commercially available drug product.” *Id.* § 353(a)(b)(1)(D); *see also* FDA Warning Letter NYK 2008-06 (Jan. 10, 2008).¹ Under FDA’s announced enforcement policy, “[t]ypically, FDA will not exercise its enforcement discretion for compounded drugs that are essentially copies of FDA-approved commercially-available drugs when there is no patient-specific medical need to

¹ Available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155170.htm>. This Court may take judicial notice of FDA Warning Letters “because they are public records which are available on the FDA’s website.” *Tierney v. AGA Med. Corp.*, No. 4:11CV3098, 2011 WL 7400469, at *4 (D. Neb. Nov. 18, 2011); *see also Stahl v. U.S. Dep’t of Agric.*, 327 F.3d 697, 700 (8th Cir. 2003) (public records can be considered on a motion to dismiss).

justify the difference.” FDA Warning Letter CIN-07-28792-06 (Dec. 1, 2006).²

B. K-V Acquires Makena, Secures FDA Approval and Orphan Drug Exclusivity, and Discloses Its Expectations to Investors

In the context of the statutory incentives to gain FDA approval for orphan drugs, K-V acquired the rights to the drug that would become known as Makena. A 2003 study suggested that a prescription hormone known as 17P, which was not commercially available as an FDA-approved drug, was effective in preventing preterm births. CAC ¶ 8. In May 2006, Adeza Biomedical Corporation submitted a NDA for a drug containing 17P (then called “Gestiva”),³ a process that involves significant research and development expense. *Id.* ¶ 9 nn. 2, 3. While that application was pending, on January 22, 2008, K-V agreed to pay \$82.5 million to acquire the rights to Makena from Adeza’s successor corporation, Hologic. *Id.* ¶ 9. Following more than three years of further FDA review, clinical trials, and expenses, FDA approved the NDA for Makena on February 4, 2011. *Id.* ¶ 10. FDA granted K-V market exclusivity for Makena under the ODA. *Id.* K-V committed an additional \$60 million to conduct major, multi-year follow-on health studies of Makena. Exh. I at 2.⁴ These expenses brought K-V’s total investment and commitment to Makena to more than a quarter of a billion dollars. *Id.*

In order to recoup its \$250 million-plus investment in Makena, and in reliance on the incentives enshrined in the FDCA and FDA’s announced enforcement policies, on a February 14, 2011 call with investors, K-V announced an initial list price of \$1,500 per injection for Makena. This represented a substantial increase over the price being charged by compounding pharmacies for a non-FDA-approved drug containing 17P. CAC ¶ 16. Mr. Divis, K-V’s CEO, announced that K-V would seek to expand access to Makena through the Makena Care Connection, which

² Available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076191.htm>.

³ For the sake of simplicity, “Makena” is used here throughout to also refer to Gestiva.

⁴ This press release and other documents cited in the CAC were incorporated by reference into the CAC and may be considered on a motion to dismiss. *Kushner v. Beverly Enters. Inc.*, 317 F.3d 820, 831-32 (8th Cir. 2003).

would include financial assistance to women with household incomes under \$100,000. *Id.*, Exh.

B at 7. During the call, Mr. Goedeke, the Senior Vice President of Marketing and Market Access at K-V's subsidiary, Ther-Rx, stated with respect to compounding pharmacies:

“[W]e believe that the regulations and laws are very clear. I think it's fair to say that compounding pharmacies are not FDA-approved manufacturing facilities and that FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products that are the same or essentially the same as FDA-approved products. We also believe that compounded pharmacies are aware of these laws and regulations, and our expectation is that they will adhere to them.”

CAC ¶ 48.

On February 17, 2011, K-V sent a letter to compounding pharmacists that had previously been manufacturing drugs containing 17P without FDA approval. CAC ¶ 50. K-V stated that, “as articulated by the FDA in numerous enforcement actions,” FDA's enforcement discretion “does not extend to compounding of copies or essentially copies of commercially available FDA-approved products.” *Id.* Accordingly, K-V stated that if the compounding pharmacies continued to manufacture 17P, they would be “subject to FDA enforcement.” *Id.*

On March 8, 2011, K-V issued a press release announcing that Makena would become available for prescribing during the week of March 14, and described its financial assistance program. CAC ¶ 52; Exh. E. K-V stated:

- **“Insured patients** with annual household incomes of up to \$100,000 who apply for and are eligible for copay assistance will have a copay of \$20 or less per injection for Makena.
- **Uninsured patients** with annual household incomes of up to \$60,000 who apply for and are eligible for patient assistance will receive Makena at no cost. Uninsured patients with annual household incomes between \$60,000 and \$100,000 will be able to acquire Makena at a cost that is comparable to the average copay assigned by commercial insurance plans.”

Exh. E at 1. On the same day, K-V filed a Form 8-K with revenue assumptions based on projected sales of Makena. CAC ¶ 54; Exh. D.

C. Under Political Pressure, FDA Takes Unprecedented Action

Only three days after Makena was first made available to patients, United States Senators

Sherrod Brown and Amy Klobuchar issued a press release expressing concern over the list price for Makena, and released a letter they had sent to the FTC urging an investigation. CAC ¶ 56; Exh. G. Although the Senators decried the list price of \$1,500 (comparing it to the lower price charged by compounding pharmacies for the non-FDA-approved drugs containing 17P), they did not mention that list prices in the pharmaceutical industry are substantially discounted such that few customers ever pay the list price. They provided no new information regarding K-V's financial assistance program. *Id.* Rather, they merely stated that “the financial assistance is not sufficient and does not extend to certain groups of women,” and noted their concern that the price would “place a heavy burden on state Medicaid programs.” *Id.* ¶ 57.

The press release also stated that Senator Brown would “grill” FDA Commissioner Margaret Hamburg, over Makena at a Senate appropriations hearing that day. Exh. G. at 1. At the hearing, Dr. Hamburg hailed FDA's approval of Makena: “I think it is important and an advance that we have an FDA-approved drug to prevent pre-term pregnancy and all of its consequent serious medical concerns for both mother and infant.” Exh. F. at 17. Dr. Hamburg also noted that “FDA does not make its approval decisions with pricing considerations.” *Id.* at 18. Senator Brown, however urged Dr. Hamburg to find some means to address concerns over Makena's price: “it is so important that we figure out something to do here. . . . ***[Y]ou need to figure out a strategy what to do here.***” *Id.* at 17 (emphasis added). The New York Times later reported that “[Obama] Administration officials then stepped in to halt any effort to ban [compounding] pharmacy-made versions [of Makena], citing the need to check an exorbitant price increase from a drug company that suddenly found itself with a monopoly. . . .” Gardiner Harris, *White House and the FDA Often at Odds*, N.Y. Times, Apr. 3, 2012, at A1.⁵

⁵ Although this news article is not cited in the Complaint, it is appropriate for this Court to consider it nonetheless. The Eastern District of New York recently cited the same article to demonstrate the political nature of FDA's deci-

“The [A]dministration instructed the FDA” to issue an unprecedented press release on March 30, 2011. *Id.* The press release stated that “[i]n order to support access to this important drug, **at this time and under this unique situation**, FDA does not intend to take enforcement action against pharmacies that compound [17P].” CAC ¶ 63 (emphasis added). This announcement represented a clear departure from FDA’s long-standing policy and marked the first time that the agency had ever declared that it would not take enforcement action against compounding pharmacies that were making copies of a commercially available FDA-approved drug.⁶ Following that declaration, a *Bloomberg* article on April 4, 2011 relayed the reservations of some doctors about the price of Makena. *Id.* ¶ 67. After these disclosures, K-V’s stock price declined.

K-V has since sued FDA for injunctive relief on the grounds that its press release encouraged violations of K-V’s statutory exclusivity. The district court ruled that FDA’s failure to enforce K-V’s exclusivity amounted to agency inaction that is unreviewable under the APA. *K-V Pharm. Co. v. FDA*, 889 F. Supp. 2d 119 (D.D.C. 2012). The case is now on appeal to the D.C. Circuit. *K-V Pharm. Co. v. FDA*, No. 12-5349 (D.C. Cir. filed Nov. 8, 2012).

III. APPLICABLE LAW

A complaint that fails “to state a claim upon which relief can be granted” is properly dismissed under Federal Rule of Civil Procedure 12(b)(6). *See Elam v. Neidorff*, 544 F.3d 921, 926 (8th Cir. 2008). Although courts “accept[] all facts pleaded therein as true” at the motion to dismiss stage, courts “reject conclusory or catch-all assertions of law and unwarranted inferences.”

sion-making, noting that judges “cannot shut our eyes to matters of public notoriety and general cognizance. . . . There comes a point where this Court should not be ignorant as judges of what we know as men and women.” *Tummino v. Hamburg*, ___ F. Supp. 2d ___, No. 12-CV-763, 2013 WL 1348656, at *7 (E.D.N.Y. Apr. 5, 2013) (citations, quotations and brackets omitted).

⁶ *See, e.g.*, Gardiner Harris, *White House and the FDA Often at Odds*, N.Y. Times, Apr. 3, 2012 at A1 (“FDA officials said they had often been wrongly accused of considering price in drug approval deliberations and had always been able to reply that price was never a factor. ‘We can’t say that anymore,’ a top FDA official said unhappily.”); Sheldon T. Bradshaw *et al.*, *Did FDA Apply a Remedy Worse Than the Disease in Refusing to Clear the Market of Unapproved Versions of Makena?*, Food and Drug Policy Forum, June 8, 2011, at 2 (“FDA’s decision . . . was a wholesale reversal of its prior position. . . .”) (Exh. J).

In re Cerner Corp. Sec. Litig., 425 F.3d 1079, 1083 (8th Cir. 2005).

Congress enacted the Private Securities Litigation Reform Act (“PSLRA”) “as a check against abusive litigation by private parties.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007); *see also In re Amdocs Ltd. Sec. Litig.*, 390 F.3d 542, 547 (8th Cir. 2004). “Exacting pleading requirements are among the control measures Congress included in the PSLRA.” *Id.* In order to survive a motion to dismiss under Rule 10b-5, a securities plaintiff must adequately plead: ““(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.”” *MEMC Elec. Materials*, 641 F.3d at 1028 (quoting *Stoneridge Inv. Partners, LLC v. Sci.-Atl., Inc.*, 552 U.S. 148, 157 (2008)).

Securities fraud claims brought under Rule 10b-5 must meet the heightened pleading requirements of the PSLRA. *Kushner*, 317 F.3d at 826. The PSLRA is a specialized pleading regime that “goes beyond the ordinary pleading requirements described in Rules 8(a)(2) and 9(b) of the Federal Rules of Civil Procedure.” *In re 2007 Novastar Fin. Inc. Sec. Litig.*, 579 F.3d 878, 882 (8th Cir. 2009).⁷ Furthermore, claims are barred where they fall into statutory safe harbors for forward-looking statements. 15 U.S.C. § 78u-5(c).

⁷ Plaintiff’s claims appear to arise under Rule 10b-5(b)—Plaintiff alleges Defendants made, or caused to be made, “untrue statement[s] of material fact.” 17 C.F.R. § 240.10b-5(b); *see e.g.* CAC ¶¶ 38-55. To the extent Plaintiff also alleges (without clearly stating) that Defendants violated Rule 10b-5(a) or (c), her claim fails. To state a claim under Rules 10b-5(a) or (c), a plaintiff must allege a “scheme . . . to defraud” or a “course of business which operates . . . as a fraud or deceit.” 17 C.F.R. § 240.10b-5(a), (c). A scheme liability claim under 10b-5(a) or (c) “must be based on conduct beyond misrepresentations or omissions actionable under Rule 10b-5(b).” *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 987 (8th Cir. 2012). “[M]isrepresentation claims under Rule 10b-5(b) cannot simply be recast as scheme liability claims under Rules 10b-5(a) and (c).” *Id.* Allegations of conduct violating 10b-5(a) and (c) must be pleaded with particularity under Fed. R. Civ. P. 9(b). *Id.* at 986. The Complaint alleges *no* facts beyond the public statements of Defendants, much less facts that would meet the heightened pleading requirements of Rule 9(b).

IV. ARGUMENT

The Complaint here should be dismissed because the challenged statements made to investors were forward-looking statements that are inactionable because they were accompanied by meaningful risk disclosures, immaterial, or made without actual knowledge of any falsity. 15 U.S.C. § 78u-5(c)(1). Other challenged statements are likewise non-actionable because they were made in private correspondence, not to the investing public. Plaintiff also fails to properly plead the elements of a securities fraud claim, including materiality, falsity, and economic harm.

A. The Challenged Statements Fall Within the PSLRA's Safe Harbor For Forward-Looking Statements Accompanied by Meaningful Cautionary Language

The PSLRA provides a safe harbor for any statement that is “identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement.”⁸ 15 U.S.C. § 78u-5(c)(1)(A)(i). The PSLRA broadly defines the categories of statements that can fall under the safe harbor. *Id.* § 78u-5(i)(1). Statements that fall within the safe harbor “are not actionable under the Exchange Act.” *W. Wash. Laborers-Emps. Pension Trust v. Panera Bread Co.*, 697 F. Supp. 2d 1081, 1096 (E.D. Mo. 2010). A forward-looking statement need not be phrased in the future-tense; rather, courts look at “whether its truth or falsity is discernible only after it is made.” *Id.* at 1093 (quoting *Harris v. Ivax Corp.*, 182 F.3d 799, 805 (11th Cir. 1999)). A statement is forward-looking if “it does not make any specific verifiable representation about the present state of affairs.” *Id.* at 1094.

To qualify as “meaningful,” a cautionary statement must “be more than mere boilerplate but less than disclosure of every potential risk.” *Id.* at 1090. Cautionary language is meaningful

⁸ There is also a separate safe harbor for any forward looking statement that is “immaterial.” 15 U.S.C. § 78u-5(c)(1)(A)(i). Defendants also dispute the materiality of the alleged misleading statements, as discussed below. *See infra* at 17-19. Likewise, there is a separate safe harbor for forward-looking statements lacking scienter. 15 U.S.C. § 78u-5(c)(1)(B). This safe harbor is also applicable, for the reasons covered below. *See infra* at 21-27.

where “it is substantive and addresses risks specific to [a company’s] business.” *Rochester Laborers Pension Fund v. Monsanto Co.*, 883 F. Supp. 2d 835, 853 (E.D. Mo. 2012). “Meaningful cautionary language need not explicitly mention the realized risk, as long as it warned of risks of similar significance.” *In re NVE Corp. Sec. Litig.*, 551 F. Supp. 2d 871, 893 (D. Minn. 2007), *aff’d*, 527 F.3d 749 (8th Cir. 2008). “[T]he cautionary language need not be a part of the forward-looking statement so long as the statement specifies where it can be located.” *Panera Bread*, 697 F. Supp. 2d at 1089-90; *see also* 15 U.S.C. § 78u-5(c)(2)(B).

The safe harbor for forward-looking statements applies *regardless* of whether the speaker knows the statement is false. *See, e.g., Panera Bread*, 697 F. Supp. 2d at 1089; *Monsanto*, 883 F. Supp. 2d at 854; *Yellen v. Hake*, 437 F. Supp. 2d 941, 961-62 (S.D. Iowa 2006).⁹ The applicability of the safe harbor is a question of law, not fact. 15 U.S.C. § 78u-5(e); *Panera Bread*, 697 F. Supp. 2d at 1089.

1. The Statements at Issue Are Identified as Forward-Looking

Plaintiff identifies eight paragraphs of allegedly misleading statements made to investors.¹⁰ The statements in each of these paragraphs were properly identified as forward looking, and included risk disclosures. Six of the paragraphs are from a conference call with investors on February 14, 2011, (CAC ¶¶ 38-49), which began with a reminder that information on the call “may contain various forward looking statements,” including “[a]ll statements that address expectations or projections about the future, including . . . the Company’s strategy for growth, product development, product launches, regulatory approvals, market position, acquisitions, revenues, expenditures and other financial results.” Exh. B at 2. The call directed listeners to the

⁹ This is in accordance with the language of the safe harbor in Section 78u-5(c)(1)(A), which contains no scienter component, in contrast with the alternative safe harbor in Section 78u-5(c)(1)(B), which does have a scienter requirement. *Id.* § 78u-5(c)(1)(B); *see Panera Bread*, 697 F. Supp. 2d at 1089.

¹⁰ Plaintiff also complains about a statement made to KV’s competitors in private correspondence. CAC ¶¶ 18, 50-51. As discussed below, this statement is non-actionable because it was not made to investors. *See infra* at 14-15.

risk “factors in our most recent annual report on Form 10-K.” *Id.* at 3; *see* Exh. A at 3-5, 39-67 (10-K risk factors). Such warnings given at the beginning of a call or presentation are sufficient to identify the relevant statements as forward looking. *See* 15 U.S.C. § 78u-5(c)(2)(B); *Monsanto*, 883 F. Supp. 2d at 863; *Gammel v. Hewlett-Packard Co.*, No. SACV 11-1404 AG, 2012 WL 5945089, at *7 (C.D. Cal. Aug. 29, 2012). Materials distributed along with the conference call, and publicly released on Form 8-K that same day, similarly identified forward-looking statements and included similar risk factors. Exh. C at 2-7. With regard to the two remaining paragraphs of allegedly misleading statements, similar language identified forward-looking statements, and risk factors were also disclosed in the March 8, 2011 Press Release and the March 8, 2011 Revenue Assumptions, which directed investors to K-V’s 10-K. Exh. D at 4, 15; Exh. E at 2-4; CAC ¶¶ 52-55.

2. K-V’s Revenue Projections Are Protected by the Safe Harbor

Plaintiff alleges that the March 8, 2011 Form 8-K contained revenue assumptions which were “unreasonable and had no basis in fact” because they did not account for the public reaction to Makena’s price and the actions of compounders. CAC ¶ 54. But the PSLRA provides that a “statement containing a projection of revenues” is protected. 15 U.S.C. § 78u-5(i)(1)(A).

Revenue projections are “quintessential” forward-looking statements. *Panera Bread*, 697 F. Supp. 2d 1081 at 1093. The revenue projections were accompanied by meaningful cautionary language. K-V warned that “[a]lthough Makena is the first and only FDA-approved treatment . . . the Company’s sales of Makena could be negatively affected by treatment of this condition by unapproved drug therapies,” such as those offered by compounders. Exh. D at 3. K-V also accounted for possible negative responses to the drug’s list price by cautioning that “[t]he Company’s ability to achieve these assumptions regarding gross and net pricing [of Makena] is subject to substantial uncertainty.” *Id.* K-V’s 2010 10-K, incorporated by reference, further warned

that exclusivity may not be realized and that the public may not accept and demand Makena. Exh. A at 2. K-V even warned that its own viability may depend on a successful launch of Makena. *Id.* at 44. These are not “disclaimers ‘that could be appended to any press release’ or public filing,” but rather meaningful risks specific to K-V’s rollout of Makena and risk regarding the viability of Makena’s list price. *See Panera Bread*, 697 F. Supp. 2d at 1092 (quoting *Sawant v. Ramsey*, 570 F. Supp. 2d 336, 342-43 (D. Conn. 2008)).

3. Statements About Patient Access Are Protected by the Safe Harbor

With regard to patient access and marketing efforts around Makena, Plaintiff alleges that Defendants made materially misleading statements relating to K-V’s commitment to ensure access for every eligible patient (CAC ¶¶ 40-41), working in concert with stakeholders to fulfill that commitment (*id.* ¶¶ 44-45), establishing a comprehensive patient financial assistance program (*id.* ¶¶ 52-53), and building a go-to market strategy. (*Id.* ¶¶ 38-39, 46-47.)

These are statements within the safe harbor for “plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer,” as each relates to the planned Makena roll-out. 15 U.S.C. § 78u-5(i)(1)(B); *see also Monsanto*, 883 F. Supp. 2d at 853 (statements regarding expected growth of business are forward-looking); *Halford v. AtriCure, Inc.*, No. 1:08cv867, 2010 WL 8973625 at *13 (S.D. Ohio Mar. 29, 2010) (projections of FDA action and market adoption are treated as forward looking statements). Each statement was made before Makena’s roll-out on March 14, 2011, and was thus necessarily forward-looking. None of these statements were verifiable statements of a present state of affairs, but rather were plans and objectives regarding future assistance programs designed to provide access to Makena. *See Panera Bread*, 697 F. Supp. 2d at 1094.

These statements were accompanied by meaningful cautionary language. K-V disclosed specific relevant risk factors, including: “new product development and launch, including the

possibility that any product launch may be delayed or unsuccessful, including with respect to Makena” and the “acceptance of and demand for the Company’s new pharmaceutical products, including Makena.” Exh. A at 2.¹¹ These factors were disclosed in the written materials accompanying the February 14, 2011 conference call, as well as in the 10-K incorporated by reference. *Id.*; Exh. C at 2-7. The language in the cautionary statements constituted “specific warnings” related to the uncertain prospects of the Company’s plans and objectives for the launch of Makena. *Monsanto*, 883 F. Supp. 2d at 853. Accordingly, the Company properly warned that demand might not meet the Company’s expectations and that the product launch might not succeed.

4. Statements About Exclusivity and Insurance Coverage Are Protected by the Safe Harbor

The remaining allegedly misleading statements are subject to the safe harbor for “any statement of the assumptions underlying or relating to” the safe harbors regarding projected financial performance, and management plans and objectives. 15 U.S.C. § 78u-5(i)(1)(D).

Plaintiff alleges that the “expectation” that compounding pharmacies “will” adhere to FDA regulations regarding the distribution of compounded products is misleading. CAC ¶ 48. This statement is forward-looking because it is merely a prediction of what compounding pharmacies would do in the future, based on K-V management’s beliefs as to what actions FDA would take, and the statement’s validity could not be assessed until Makena was released and the compounders responded. *See Halford* 2010 WL 8973625 at *13 (projections regarding FDA action are treated as forward looking statements). The statement was accompanied by meaningful cautionary language because K-V specifically warned of “the possibility that any period of exclusivity may not be realized, including with respect to Makena” and of “the impact of competitive . . . response . . . to the Company’s sales . . . including introduction or potential introduction

¹¹ The FY 2010 10-K also contains detailed disclosures of these and other risk factors. *See* Exh. A at 39-67.

of generic or competing products . . . against products sold by us and our subsidiaries, including [Makena], and including competitive or responsive pricing changes.” Exh. A at 2.

Plaintiff also alleges that the statement, “we anticipate that commercial payers and state Medicaid programs will cover and reimburse Makena” is misleading because commercial payers and Medicaid programs could resist paying for Makena. CAC ¶¶ 42-43. This statement was forward-looking because it would have been impossible determine at that time whether and to what extent commercial and Medicaid payers would cover Makena. *See Panera Bread*, 697 F. Supp. 2d at 1093. K-V provided meaningful cautionary language that there was a risk regarding the “acceptance of and demand for the Company’s new pharmaceutical products, including Makena.” Exh. A at 2. K-V further warned that “reimbursement policies of third parties may affect the marketing of our products” and that “[o]ur ability to market our products will depend in part on reimbursement levels for the cost of the products and related treatment established by health care providers, including government authorities, private health insurers and other organizations.” *Id.* at 68. This risk discussion was related to the specific challenges facing K-V’s business with regards to gaining acceptance for Makena and reimbursements from insurers. *See Monsanto*, 883 F. Supp. 2d at 853.

B. Plaintiff Cannot Challenge Statements That Were Not Made to Investors

Under Rule 10b-5, a securities plaintiff must properly allege that the challenged statement was made “in connection with the purchase or sale of any security.” *See* 17 C.F.R. § 240.10b-5(c); *Klaers v. St. Peter*, 942 F.2d 535, 538 (8th Cir. 1991). Plaintiffs must therefore allege that the alleged false statements were made “in a manner reasonably calculated to influence the investing public.” *Basic Inc. v. Levinson*, 485 U.S. 224, 235 n. 13 (1988); *see also Rowinski v. Salomon Smith Barney Inc.*, 398 F.3d 294, 301 (3d Cir. 2005) (statements must be “disseminated to the public in a medium upon which a reasonable investor would rely.”).

Plaintiff challenges statements made by K-V in “a letter to compounding pharmacists” on February 17, 2011, but she does not allege that such statements were ever made available to investors or that K-V sent the letter in order to influence the investing public. CAC ¶¶ 18, 50-51. Where plaintiffs fail to allege that statements are intended or expected to be used in connection with the purchase or sale of a Company’s shares, they fail to state a claim for which relief can be granted. *See Landy v. Fed. Deposit Ins. Corp.*, 486 F.2d 139, 168 (3d Cir. 1973) (financial reports did not satisfy connection requirement because defendant did not “expect them to be used in connection with the purchase or sale” of the company’s stock). Letters sent to officers of a company, not in their capacity as a member of the investing public, do not form the basis for a claim of securities fraud. *See Jabend, Inc. v. Four-Phase Sys., Inc.*, 631 F. Supp. 1339, 1344 (W.D. Wash. 1986). Companies regularly send letters to other market participants asserting their interpretation of the law or predictions about the market, without including “safe harbor” disclosures or discussing “forward looking statements,” because they are not connected with sales of securities. Normal, inter-company communications are not subject to the securities laws.

C. Plaintiff Has Failed to Plead Facts that Necessarily Show that the Purported Misstatements Were Materially False or Misleading

Under the heightened pleading standard of the PSLRA, a complaint must “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading” and “why the alleged misstatements would have been false or misleading *at the several points in time in which it is alleged they were made.*” 15 U.S.C. § 78u-4(b); *In re Cerner*, 425 F.3d at 1083 (emphasis added). Allegations of misrepresentation must be supported by facts that “must *necessarily show* that the defendants’ statements were misleading.” *In re Cerner*, 425 F.3d at 1083 (emphasis added).

1. Statements About Makena's Exclusivity Were True When Made

Plaintiff challenges a number of statements made by K-V regarding its market exclusivity over Makena and regulations applicable to compounding pharmacies. CAC ¶¶ 48-51. But all of the challenged statements regarding FDA regulations and policy are specifically supported by the regulations themselves or by previous FDA positions.

- *Compare* February 14 statement that “FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products that are the same or essentially the same as FDA-approved products,” CAC ¶ 48, *with* 21 U.S.C. § 353a(b)(1)(D) (pharmacists must not compound “regularly or in inordinate amounts” drugs that “are essentially copies of a commercially available drug product”); FDA Warning Letter NYK 2008-06 (Jan. 10, 2008) (unlawful to compound “copies or near-copies of FDA-approved drug[s]” “without a medical need for their variation from the FDA-approved, commercially-available drugs”).
- *Compare* February 17 letter stating that compounded formulations of the drug “should no longer be made” and that FDA’s enforcement discretion “does not extend to compounding of copies or essential copies of commercially available FDA-approved products,” CAC ¶ 51, *with* FDA Warning Letter CIN-07-28792-06 (Dec. 1, 2006) (“Typically FDA will not exercise its enforcement discretion for compounded drugs that are essentially copies of FDA-approved commercially-available drugs. . . .”).

Because K-V accurately summarized the law and FDA policy up until that time, Plaintiff cannot plead facts that “necessarily show” that the challenged statements were false when made.

Plaintiff also alleges that Mr. Divis falsely stated that K-V’s “expectation is that [compounding pharmacies] will adhere to [the laws and regulations].” CAC ¶ 48. But “in order to plead that an opinion is a false factual statement . . . , the complaint must allege that the opinion expressed was different from the opinion actually held by the speaker.” *Nolte v. Capital One Fin. Corp.*, 390 F.3d 311, 315 (4th Cir. 2004) (citing *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1093 (1991)). Under this standard, “a complaint must show that the statement in question is grounded on a specific factual premise that is false, and that the speaker did not ‘genuinely or reasonably believe’ it.” *In re Longtop Fin. Techs. Ltd. Sec. Litig.*, 11 Civ. 3658, 2012 WL 5512176, at *10 (S.D.N.Y. Nov. 14, 2012). Plaintiff pled no facts to show that Mr. Divis did not

genuinely or reasonably believe that compounding pharmacies would follow the law.

Plaintiff relies upon a confidential witness (“CW1”) who purportedly told Defendants Divis and Goedeke, prior to February 14, that “the FDA would not preclude compounding pharmacies from producing the drug based on his/her past experience” and that “it is difficult and expensive for the FDA to police all the compounding pharmacies.” CAC ¶ 49. Allegations sourced from confidential witnesses are not reliable and should be disregarded. *See MEMC Elec. Materials*, 641 F.3d 1023 at 1030 (citing *Higginbotham v. Baxter Int’l Inc.*, 495 F.3d 753, 757–58 (7th Cir. 2007)) (“It is hard to see how information from anonymous sources could be deemed ‘compelling’ or how we could take account of plausible opposing inference. Perhaps these confidential sources have axes to grind. Perhaps they are lying. Perhaps they don’t even exist.”)). Moreover, the Complaint alleges no facts establishing that Messrs. Divis and Goedke must have believed CW1’s unsupported predictions. Without fact-based allegations that the “managers adopted [CW1’s] opinion but then publicly declared” the opposite, Plaintiff fails to plead falsity. *Nolte*, 390 F.3d at 316.

Plaintiff also cites a March 30, 2011 FDA press release, where the agency, under tremendous political pressure from Congress and the White House, stated that it would not take “enforcement action against pharmacies that compound [drugs containing 17P].” Ex. H. At most, this document establishes that Defendants failed to predict that the FDA would take unprecedented action. Such allegations amount to nothing more than impermissible fraud by hindsight allegations. *See In re Cerner*, 425 F.3d at 1083 (plaintiff “must indicate why the alleged misstatements would have been false or misleading at the several points in time which it is alleged they were made.”); *In re Navarre Corp. Sec. Litig.*, 299 F.3d at 743.

2. Plaintiff Fails to Establish that Statements Regarding Patient Access to and Marketing of Makena were Necessarily False

Plaintiff alleges that Defendants' statements regarding K-V's planned efforts to facilitate access to Makena for every eligible patient and "working in concert with stakeholders to help ensure that all eligible patients have access" were materially misleading because Defendants purportedly were aware that Makena's list price "would not 'facilitate access' for every available patient," the financial assistance provided through Makena Care Connection was inadequate because it did not extend to certain groups of women, and Defendants ignored the March of Dimes in their marketing approach for Makena. CAC ¶¶ 38-41, 44-47, 52-53.

As an initial matter, these statements are inactionable because they are immaterial puffery. "[S]ome statements are so vague and such obvious hyperbole that no reasonable investor would rely upon them." *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 547 (8th Cir. 1997). A statement that a company is "well positioned" with regard to upcoming products is too vague to be considered material. *In re Hutchinson Tech. Inc. Sec. Litig.*, 536 F.3d 952, 962 (8th Cir. 2008). So is a statement that a company "anticipate[s]" or "expect[s]" increased demand for its products. *In re Daktronics, Inc. Sec Litig.*, No. CIV 08-4176, 2010 WL 2332730, at *14 (D.S.D. June 9, 2010).

Here, the identified statements relating to patient access and marketing efforts refer to expectations for access and marketing in such general and optimistic terms that no reasonable investor would rely on them. Statements that KV created a market strategy to "ensure that we are in a position to help fulfill the promise of Makena by facilitating access," CAC ¶¶ 38-39, or that "we need to do everything we can to ensure every eligible mom has access," *id.* ¶¶ 46-47, are "vague and [] obvious hyperbole" such that "[n]o reasonable investor would rely upon them." *See Parnes*, 122 F.3d at 547. Such management-speak is immaterial puffery as a matter of law.

See Panera Bread, 697 F. Supp. 2d at 1094 n.5. K-V’s statements about how much financial assistance it would provide were further immaterial to investors because a reasonable investor would not choose to purchase K-V’s stock because it committed to giving away large amounts of free and discounted product. Therefore, even if those statements turned out to be false, the reasonable investor would not find the revelation of falsity material. *See Okla. Firefighters Pension & Ret. Sys. v. Capella Educ. Co.*, 873 F. Supp. 2d 1070, 1080 (D. Minn. 2012).

Plaintiff has also failed to establish that these statements were materially misleading. Plaintiff alleges that Defendants were aware that the \$1,500 per injection price point would not ensure access for every eligible patient. CAC ¶ 41. Plaintiff also alleges that the statement that K-V expected government and commercial payers to cover Makena was misleading. *Id.* ¶¶ 42–43. Plaintiff’s sole factual basis for alleging that Defendants’ statements were misleading is a confidential witness (“CW2”) reporting that K-V held a conference months before the launch of Makena where salespersons were trained to deal with “‘push back’ from physicians, because they knew ‘physicians would be shocked by the price.’” *Id.* ¶¶ 14, 43. Even apart from the unreliability of confidential witnesses, *see supra* at 17, this allegation merely reveals that Defendants planned to persuade doctors to prescribe Makena, and such planning demonstrates that Defendants were working to widen access to Makena. Nor does planning for potential pushback contradict statements that government and commercial payers were ultimately anticipated to cover Makena. CAC ¶¶ 42–43. Finally, as discussed above, *see supra* at 17, mere disagreement among employees fails to render these statements misleading. *See Nolte*, 390 F.3d at 316.

Plaintiff also alleges that Defendants’ statements regarding facilitating access to every eligible patient was materially misleading because “certain uninsured and lower income bracket women were excluded” from the Makena Care Connection. CAC ¶ 47; *see id.* ¶ 45. This bare

assertion lacks any factual support. Plaintiff's primary allegation that the program was deficient is one sentence from the Senators' March 17, 2011 letter to the Federal Trade Commission, where they state that the "financial assistance is not sufficient and does not extend to certain groups of women." *Id.* ¶ 57. But the Senators based this statement on K-V's previous statements about available financial assistance, not on any additional facts. *See* Exh. G. Moreover, the statement is entirely conclusory—it does not say which women were excluded from the program or what level of financial assistance would be considered "sufficient." *Id.* That the speakers were public officials does not cure the allegations' lack of substance. *See In re Fannie Mae 2008 Sec. Litig.*, 891 F. Supp. 2d 458, 474 (S.D.N.Y. 2012) (e-mail from a White House economist to a Treasury Official was too "conclusory" to prove falsity).

Plaintiff's Complaint also references CW1 stating that the Makena Care Connection program was the worst "he/she had ever seen, and it was a 'tremendous screw up.'" CAC ¶ 16. But any purported failings in the program had nothing to do with the program's genuine goals. Moreover, the reference lacks the specificity required by the PSLRA, as it is unclear in what ways the MCC was a "screw up" (*e.g.*, whether it faced administrative difficulties, challenges in its initial launch, or actually failed to provide the intended financial assistance), or even whether it was a "screw up" during the putative Class Period.

Finally, Plaintiff alleges that Mr. Divis's statement that K-V believed its "go-to-market strategy" would put it in a position "to reach out to a requisite number of health care professionals to surround the major majority of the business opportunities that exist" was materially misleading because K-V ignored the March of Dimes in its marketing approach. CAC ¶ 47. But Plaintiff admits that the March of Dimes was invited to, and attended, a KV conference where Makena was discussed, which belies the assertion that Defendants were "ignoring" the March of

Dimes. *Id.* ¶¶ 14-15. The sole basis on which Plaintiff makes this assertion is confidential witness criticism of the marketing approach to the March of Dimes. *Id.* ¶¶ 15, 20. Plaintiff again relies upon an unreliable confidential witness who purportedly stated a personal opinion that the March of Dimes would react poorly to the price of Makena. But mere disagreement by an anonymous employee does not render Defendants' statements materially misleading, and Defendants were not required to be clairvoyant about how the March of Dimes would react. Plaintiff also fails to allege how the March of Dimes' reaction, standing alone, made the statement untrue.

3. Plaintiff Fails to Establish that Defendants' Revenue Projections Were Materially Misleading

Plaintiff alleges that K-V's revenue projections were "unreasonable and had no basis in fact" because "[t]hey did not account for the anticipated backlash that the Company received from the FDA, physicians, the March of Dimes, and others . . . nor did they account for the compounding of the drug by pharmacies that would crush K-V's profit margin." CAC ¶¶ 54-55.

The revenue projections here are also opinions. Plaintiff's allegation is derivative of her other allegations that Defendants ignored potential backlash from various stakeholders and had no reasonable basis to believe that FDA would continue to follow its long-standing enforcement policy, but Plaintiff has not pled facts demonstrating that either proposition is true. Plaintiff also fails to plead, with specificity, that these Defendants did not reasonably believe the accuracy of the revenue projections when the Form 8-K was filed.

D. Plaintiff Fails to Allege Facts Justifying a Strong Inference of Scienter.

In addition to requiring that falsity be pled with particularity, the PSLRA also heightens the pleading requirements with regard to scienter. *See In re Navarre*, 299 F.3d at 742. In order to plead liability under § 10(b) and Rule 10b-5, Plaintiff is required to allege particular facts that create a strong inference "for each defendant and with respect to each alleged misrepresentation"

that the alleged misrepresentation was made with “scienter, *i.e.*, a wrongful state of mind.”

Horizon Asset Mgmt. Inc. v. H & R Block, Inc., 580 F.3d 755, 760, 761 (8th Cir. 2009); *see also In re Ceridian Corp. Sec. Litig.*, 542 F.3d 240, 246 (8th Cir. 2008).

1. Plaintiff Pleads No Facts Showing Scienter For Mr. McHugh

Plaintiff identifies no particular alleged misrepresentations made by Mr. McHugh, and with respect to scienter, alleges only that he was, “at all relevant times[] the Company’s CFO. During the Class Period, Mr. McHugh signed and certified the Company’s . . . SEC filings that contained materially false and misleading statement [*sic*] about Makena.”¹² CAC ¶ 78. The only SEC filing at issue in this case, however, is the March 8, 2011 Form 8-K signed by Mr. Divis, which makes no mention whatsoever of Mr. McHugh. *Id.* ¶ 54; Exh. D.

2. Plaintiff Fails to Plead Scienter For Mr. Goedeke or Mr. Divis.

With respect to Mr. Goedeke and Mr. Divis, Plaintiff makes no allegations of insider trading, self-dealing, or any individual motive to commit securities fraud. Plaintiff alleges only that certain “confidential witnesses” who worked for Messrs. Goedeke and Divis disagreed with them about the likely future outcome of K-V’s plans and expectations about ODA exclusivity (*see* CAC ¶¶ 10, 11, 19, 43, 49, and 70), future patient access (*id.* ¶¶ 39, 47, and 62), and future marketability based on the expected base price of Makena (*id.* ¶¶ 11, 15, 20, 39, 43, 47, 70, and 76). These allegations are insufficient to plead scienter.

a. Plaintiff Must Allege Defendants’ Actual Knowledge of Falsity.

As explained above, because the statements at issue were forward-looking and accompanied by meaningful cautionary language, the PSLRA states that such statements are not actiona-

¹² Plaintiff’s other allegations about Mr. McHugh lump him in with the “Individual Defendants” and the insufficient general allegations of Defendants’ knowledge about the Company’s Makena strategy by virtue of their professional backgrounds, titles, and roles, and Makena’s importance to the Company, but are devoid of any allegation that they had actual knowledge of falsity. CAC ¶¶ 79-81, 83, 88-91.

ble even if the speakers knew they were false. *Supra* at 10. But even if cautionary language is insufficient or lacking, where, as here, the statements at issue are all forward-looking, *see supra* at 11-14, “the required level of scienter is *actual knowledge*.” *Matrixx Initiatives, Inc. v. Siracusano*, ___ U.S. ___, 131 S. Ct. 1309, 1324 n. 14 (2011) (emphasis added); 15 U.S.C. § 78u-5(c)(1)(B).¹³ This is because the scienter requirement conforms with the statutory safe harbor making inactionable forward-looking statements that are made without actual knowledge, even if not accompanied by meaningful cautionary language. *Id.* § 78u-5(c)(1)(B).¹⁴ To allege actual knowledge, Plaintiff must plead that the Defendants: (1) *did not genuinely believe* the statement when made, (2) *actually knew* they had no reasonable basis for making the statement, or (3) *were aware of undisclosed facts* tending to seriously undermine the accuracy of the statement. *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 775 (2d Cir. 2010); *Rabbani*, 2012 WL 5395787, at *10.

Additionally, the PSLRA’s heightened pleading rules require Plaintiff to “state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind,” of actual knowledge. *Matrixx Initiatives*, 131 S. Ct. at 1323-24 (quoting 15 U.S.C. § 78u-4(b)(2)(A)) (emphasis added). To support such a strong inference, the Court must take into account opposing inferences, and Plaintiff “must plead facts rendering an inference of scienter *at least as likely* as any plausible opposing inference.” *Tellabs*, 551 U.S. at 323-24, 328; *see also MEMC Elec. Materials*, 641 F.3d at 1029.

¹³ Although “severe recklessness” can be a basis for scienter in some contexts, *see Horizon Asset Mgmt., Inc.*, 580 F.3d at 766, the Supreme Court has found that actual knowledge of falsity is required for liability regarding forward-looking statements. *Matrixx Initiatives, Inc.*, 131 S. Ct. at 1324 n. 14. *See also City of Livonia Emps.’ Ret. Sys. & Local 295/Local 851 v. Boeing Co.*, Nos. 12-1899, 12-2009, 2013 WL 1197791, at *2 (7th Cir. Mar. 26, 2013) (Posner, J.); *Rabbani v. DryShips Inc.*, No. 4:12CV130 RWS, 2012 WL 5395787, at *4 (E.D. Mo. Nov. 6, 2012). By definition, the actual knowledge requirement precludes severe recklessness as a basis for scienter. *Boeing Co.*, 2013 WL 1197791 at *2; *Slayton*, 604 F.3d at 773. Even if the severe recklessness standard were applicable, however, Plaintiff’s generic allegations of recklessness here would not save her claim. Plaintiff would be required to allege “highly unreasonable omissions or misrepresentations amounting to an extreme departure from the standards of ordinary care, and that present a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of it.” *Horizon Asset Mgmt., Inc.*, 580 F.3d at 766 (*quoting Kushner*, 317 F.3d at 828). Plaintiff has not done so.

¹⁴ The scienter analysis likewise makes the safe harbor applicable here. 15 U.S.C. § 78u-5(c)(1)(B).

b. The Most Plausible Inference Is that Defendants Believed that Makena Would Be a Success.

Plaintiff's supposed inference of fraud is highly improbable compared to the far more compelling inference that Defendants believed K-V could successfully market Makena and that their business judgment was that the best way to do so was by selling Makena at the list price of \$1,500 per injection with a patient financial assistance program. Plaintiff *admits* that K-V pursued Makena "as a lifeline" and that its success was of "critical importance of Makena to the Company's survival." CAC ¶ 7. Plaintiff *admits* that K-V invested more than \$82.5 million to develop, produce, and sell Makena under the ODA¹⁵, *id.* ¶ 9, that "FDA granted K-V's request for ODA protection on February 4, 2011," *id.* ¶ 10, and that "the ODA provides seven years of exclusive sales rights to manufacturers who win FDA approval." *Id.* ¶ 9.

Further, Plaintiff *specifically alleges* that K-V selected the \$1,500 list price because Messrs. "Divis and Goedeke . . . wanted to have a \$4 billion company and that the \$1,500 per injection price for Makena could make that happen." CAC ¶ 11. Plaintiff *admits* that K-V stated that it believed commercial payers would pay this price because "pre-term birth can be very costly to a health plan" – more than \$51,000 in the first year alone – and that "Makena can help offset some of those costs." *Id.* ¶ 42; Exh. B at 6-7, 13. Mr. Goedeke further stated that "with the approval in hand," K-V was prepared to "quickly execute a plan that we have in place to get out and see all of the top commercial, state and also managed Medicaid payers." CAC ¶ 14. Plaintiff *admits* that, in preparation for addressing price issues, "prior to the launch of Makena" K-V conducted a "several-day-long training conference" that was "dedicated" to addressing potential market responses to the "very expensive" price of Makena. *Id.* And Plaintiff *admits* that K-V further addressed potential price concerns by creating a program designed to provide significant

¹⁵ KV's April 1, 2011 Form 8-K, also cited by Plaintiff, reveals that K-V actually spent or committed more than \$250 million for Makena. Exh. I at 2.

discounts to “approximately 85% of U.S. households.” *Id.* ¶ 44.

Given the admitted importance of successfully marketing Makena to K-V’s future survival, the significant, multi-year, multi-million dollar investment K-V made in the drug, the ODA’s provision for market exclusivity, FDA’s then-existing policy, and K-V’s comprehensive training and customer care discounts to support the sales price, the simplest, most cogent, and most logical explanation is that Messrs. Divis, McHugh, and Goedeke, in fact, believed that K-V’s strategy to sell Makena at the \$1,500 per dose base price point would succeed.

Against this highly plausible scenario, Plaintiff suggests that Defendants’ representations evinced a plan for Makena in which hundreds of millions of dollars were devoted to a strategy that Defendants knew would inevitably fail because Defendants *knowingly*: (1) set a list price for Makena that was so high that virtually no one would buy it when it was released *in the future*, (2) expected that FDA would depart from longstanding enforcement policies and refuse to enforce KV’s ODA exclusivity *in the future*, and (3) planned a financial assistance program that some market participants would find insufficient *in the future*. All of this, Plaintiff suggests, was undertaken *on purpose* for the “intended effect of causing K-V’s shares to trade at artificially inflated levels” for a brief period before the market realized that Defendants had “lied,” though Plaintiff does not (and cannot) allege a single stock sale or individual benefit for any Defendant. CAC ¶ 95; *see In re Travelzoo Inc. Sec. Litig.*, No. 11 CIV. 5531 & 6845 GBD, 2013 WL 1287342, at *9 (S.D.N.Y. Mar. 29, 2013). Defendants supposedly did all this not in order to make K-V into a “\$4 billion company,” as Messrs. Goedeke and Divis allegedly stated, but instead because it would allow the Company to take on additional financing. CAC ¶¶ 85-87. But the financing deals were not dependent on K-V’s stock price, and a portion of the capital raised was used to fund the rollout of Makena. *See* CAC ¶ 86. This scenario is not plausible.

c. Plaintiff's Scienter Allegations Are Legally Insufficient.

Plaintiff's heavy reliance on "confidential witnesses" is misplaced, because this Court should "disregard . . . reliance on the allegations of confidential sources." *MEMC Elec. Materials, Inc.*, 641 F.3d at 1030; *see also Boeing Co.*, 2013 WL 1197791 at * 5. According to the Complaint, CW1 here only claims to have *predicted* to Messrs. Goedeke and Divis that "FDA would not prevent compounding pharmacies from manufacturing the drug" and that Makena's anticipated \$1,500 price "would compromise the Company's relationships with Makena proponents." CAC ¶ 70. CW1 was merely reporting his own subjective *judgment* about what *might* happen in the market in the future. Even under Plaintiff's allegations, CW1 *does not* claim he spoke to FDA, March of Dimes, any Medicaid agency, or any "Makena proponents," or otherwise possessed knowledge of, or conveyed any, specific plans of any of these parties. The fact that K-V management through its own judgment ultimately reached a different conclusion from CW1 "fall[s] short of scienter in the context of securities fraud." *Ashland, Inc. v. Oppenheimer & Co.*, 648 F.3d 461, 470 (6th Cir. 2011); *see also Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 998 (9th Cir. 2009) (confidential witness allegations that "demonstrate only that there was some disagreement within the corporation" do not plead scienter even under recklessness standard); *In re Medicis Pharm. Corp. Sec. Litig.*, 689 F. Supp. 2d 1192, 1211 (D. Ariz. 2009) ("vague allegations of disagreement and concern" by confidential witness "are insufficient to satisfy the scienter requirement for securities fraud").

That Makena is a "core product" does not demonstrate scienter. CAC ¶¶ 81-83. The Eighth Circuit has expressly declined to "determine whether the core operations approach can be utilized to plead scienter." *Elam*, 544 F.3d at 929. Even if the doctrine were applied, Plaintiff must show that the information making the representations false was known within the company at the time of the statement. *Id.* Plaintiff does not allege that Defendants, or anyone, *actually*

knew that the market would react negatively to the price or assistance programs, or that FDA would not enforce exclusivity.

Likewise, Defendants' professional backgrounds and high-level positions within K-V do not support scienter absent actual knowledge of a fraud. *In re Level 3 Commc'ns, Inc. Sec. Litig.*, 667 F.3d 1331, 1344 n.13 (10th Cir. 2012). Although Plaintiff alleges cryptically that the Defendants' positions at K-V gave them "access to the adverse undisclosed information about K-V's business prospects," CAC ¶ 90, the Complaint fails to identify this mystery information.

Finally, Plaintiff alleges that the motive behind Defendants' alleged fraud was to enable K-V to raise financing so that the Company could "continue as a going concern." "The desire to make a company seem more profitable is a desire universally held among corporations and their executives, and thus insufficient to support an inference of scienter, even when tied to a debt offering." *Horizon Asset Mgmt. Inc.*, 580 F.3d at 766 (internal quotations omitted); *see also In re K-tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 894 (8th Cir. 2002). Furthermore, Plaintiff does not allege that the \$200 million of secured notes or the \$32 million private placement were dependent on the Company's allegedly inflated stock price.¹⁶ CAC ¶¶ 84-87.

E. Plaintiff Fails to Properly Plead Loss Causation.

"To adequately plead loss causation, the complaint must state facts showing a causal connection between the defendant's misstatements and the plaintiff's losses." *McAdams v. McCord*, 584 F.3d 1111, 1114 (8th Cir. 2009). Plaintiff must establish "that the loss was foreseeable" and that "the defendant's fraud – and not other events – caused the security's drop in price." *Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 550 (8th Cir. 2008). A plaintiff must also allege that the fraud was disclosed to the market, otherwise a reduced stock price "may reflect, not the earlier misrepresentation, but" other factors, "which taken separately or together

¹⁶ In actuality, the secured notes totaled \$225 million, but the difference is irrelevant for this motion.

account for some or all of that lower price.” *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 342-43 (2005). Information already known by the market is not a corrective disclosure. *Meyer v. Greene*, 710 F.3d 1189, 1199 (11th Cir. 2013); *Katyle v. Penn Nat’l Gaming, Inc.*, 637 F.3d 462, 473 (4th Cir. 2011), *cert. denied*, 132 S. Ct. 115 (2011).

Here, none of the alleged corrective disclosures reveal any misrepresentations or suggest that any Defendant had actual knowledge of the fraud. Instead, the disclosures are backlashes to the properly-disclosed price of Makena; it is this backlash that resulted in a decline in K-V’s stock price. *See, e.g., Okla. Firefighters*, 873 F. Supp. 2d at 1086. “[N]ot every bit of bad news that has a negative effect on the price of a security necessarily has a *corrective* effect for purposes of loss causation.” *Meyer*, 710 F.3d at 1202.

1. March 17, 2011 Press Release

On March 17, 2011, Senators Brown and Klobuchar issued a press release to announce their concern that K-V had “monopoliz[ed]” Makena and that its proposed list price “could” result in fewer women being able to afford the drug. CAC ¶ 56-57. The press release did not reveal any undisclosed facts, but provided opinions on facts already disclosed. *See, e.g., Katyle*, 637 F.3d at 478. While the Senators may have believed that K-V’s previously disclosed financial assistance should have been more generous or that K-V should have set a lower list price, “a negative . . . characterization of previously disclosed facts does not constitute a corrective disclosure.” *See In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 512 (2d Cir. 2010).

Further, the Senators’ request for an FTC investigation does not constitute a corrective disclosure. *See Meyer*, 710 F.3d at 1202; *In re Omnicom Grp.*, 597 F.3d at 511. Nor does it support loss causation because investors understandably became nervous when Senators lambasted a company and requested a government investigation. *See Okla. Firefighters*, 873 F. Supp. 2d at 1086 (stock drop was a likely reaction to governmental announcements relating to

the regulation of the industry); *Meyer*, 710 F.3d at 1202.

2. March 23, 2011 Letter from the March of Dimes

On March 23, 2011, the March of Dimes wrote a private letter to Ther-Rx. CAC ¶ 59. Plaintiffs do not allege that the letter caused any drop in K-V's stock price. Thus, it does not support loss causation. *See McAdams*, 584 F.3d at 1114-15.

3. March 30, 2011 K-V Press Release

K-V's March 30, 2011 press release responded to feedback from the market concerning the list price of Makena and indicated K-V would propose solutions within a few days, which it did. CAC ¶ 61; *see* Exh. I at 1-2. Nothing in the press release revealed any alleged fraud; it only announced K-V's intent to make Makena more affordable to more women. *See Okla. Firefighters*, 873 F. Supp. 2d at 1084-86 (no loss causation where fraud was not revealed).

4. March 30, 2011 FDA Press Release

On March 30, 2011, FDA issued a press release contradicting private letters that K-V had sent to compounding pharmacies and announcing that FDA would withhold enforcement against compounded drugs containing 17P. CAC ¶ 63. Because the letters K-V sent to compounders were not communications to the market, they are not actionable misrepresentations, *see supra* at 14-15. FDA's March 30 press release is thus irrelevant for purposes of loss causation.

Moreover, the press release does not constitute a corrective statement because K-V's letter to compounders summarized what had been "articulated by the FDA in numerous [prior] enforcement actions" and stated that compounders would be "subject to FDA enforcement." CAC ¶ 50. The FDA press release states only that it had decided to change its enforcement priorities "at this time and *under this unique situation*." *Id.* ¶ 63 (emphasis added). The press release also did not correct the statement that FDA regulations "generally prohibit the distribution of compounded products that are the same or essentially the same as FDA-approved products." *Id.* ¶

48. Instead, the press release announced that FDA would be exercising “enforcement discretion,” or choosing not to enforce the laws. The release did not reveal fraud.

5. April 1, 2011 K-V Press Release

On April 1, 2011, K-V announced that it would take further efforts to reduce the cost of Makena. CAC ¶ 65. The statement merely announced a price decrease in response to market backlash, and did not “reveal what Plaintiff alleges had been fraudulently omitted.” Thus, it was not a corrective disclosure. *See Okla. Firefighters*, 873 F. Supp. 2d at 1086.

6. April 4, 2011 Bloomberg Article

On April 4, 2011, Bloomberg published an article reacting to the original price of Makena and the price-decrease K-V announced on April 1, 2011. CAC ¶ 67. The article’s inclusion of opinions of various doctors has no relation to any alleged fraud and does not identify any fraud. It focuses only on the list price of Makena and how a handful of physicians were hesitant to prescribe Makena. K-V, however, never represented that all doctors would prescribe Makena or would view its list price favorably. Thus, this article cannot support loss causation.¹⁷

F. Plaintiff Fails to State a Claim Under Section 20 of the Exchange Act.

Plaintiff also brings a claim against Defendants as “controlling persons” under Section 20 of the Exchange Act. There can be no Section 20 claim without an underlying securities violation. *Deviries v. Prudential-Bache Sec., Inc.*, 805 F.2d 326, 329 (8th Cir. 1986). Plaintiff has not pleaded a violation of the Exchange Act, and thus her § 20 claim must be dismissed as well.

V. CONCLUSION

For the foregoing reasons, the Complaint should be dismissed with prejudice.

¹⁷ Although Plaintiff claims that “the market absorbed this news over the next 90 days” causing further losses, CAC ¶ 68, she alleges no further disclosures nor any basis to support causation. *See, e.g., In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d at 553 (no loss causation where market reacted long after the disclosure); *McAdams*, 584 F.3d at 1114-15 (“threadbare[] conclusory statement[s]” insufficient to allege loss causation).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true copy of the foregoing document was served electronically via the CM/ECF system on all counsel of record on this 22nd day of April, 2013.

/s/ Robert P. Berry